UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BONNIE COOPER, on behalf of herself and all others similarly situated, Plaintiff, v. WAL-MART STORES, INC., Defendant.	No. 1:13-cv-05446-JBS-JS

DEFENDANT WAL-MART STORES, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(6) OR, IN THE ALTERNATIVE, TO STRIKE PLAINTIFF'S CLASS ALLEGATIONS PURSUANT TO FED. R. CIV. P. 23(d)(1)(D)

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PRELIMINARY STATEMENT

Plaintiff asserts a single claim under the New Jersey Consumer Fraud Act, N.J.S.A. § 56-8:2 *et seq*. ("CFA"), against Wal-Mart in connection with its marketing and sale of an over-the-counter pain relief medication, equate® Migraine Relief ("Equate Migraine"). Plaintiff's inventive theory is that she was deceived into purchasing Equate Migraine because a different, less-expensive product sold by Wal-Mart, which she did **not** buy, equate® Extra Strength Headache Relief ("Equate Headache"), contains the same ingredients as Equate Migraine, but does not make the same migraine relief claim. Plaintiff alleges that the claim on Equate Migraine is therefore somehow deceptive. Plaintiff's complaint is legally-deficient for several reasons, however.

First, Plaintiff is complaining about the labeling on an over-the-counter drug product that is subject to a federal regulatory process, administered by the Food and Drug Administration ("FDA") pursuant to the requirements of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §301 *et seq*. To accept Plaintiff's theory about what the labeling should have said on either product would require Wal-Mart to violate the FDCA and its implementing regulations. Accordingly, Plaintiff's claim is both expressly and impliedly preempted as a matter of law.

Second, even if Plaintiff's claim were not preempted, it involves a labeling claim that is within the jurisdiction of the FDA, which has expertise regarding the interpretation of its own regulations governing the labeling on the product involved in this case. Therefore, the Court should defer to the FDA and decline jurisdiction in accordance with the primary jurisdiction doctrine.

Third, the allegations of the Complaint do not state a cognizable cause of action under the CFA. Plaintiff does not allege that the product label on Equate Migraine misstates the active ingredients of the product, or that any of the claims on the Equate Migraine label are false. Nor does Plaintiff claim that the product does not treat migraine headaches, or that she did not receive the product marketed as Equate Migraine. The allegations of the Complaint do not challenge the effectiveness of Equate Migraine in providing migraine relief, do not allege that it failed to provide relief to plaintiff, and do not raise any safety issues. Therefore, there is no claim under the CFA based on the product's labeling.

Further, there is no support for Plaintiff's theory that a difference in price between two products is sufficient to sustain a claim of deceptive marketing under the CFA. In fact, the case law is to the contrary. The price differential between the Equate Migraine product and the Equate Headache product, far from being an attempt to "mislead" consumers, reflects the fact that Wal-Mart can only sell a product with a migraine claim if the manufacturer has complied with the FDA's

regulatory process for labeling such medications; the same regulatory process does not apply to the headache product. What plaintiff is seeking in this case is a windfall based on her allegation that there is a different and less expensive product in the marketplace that she would have found equally satisfactory. The CFA does not provide a cause of action for such claims, however.

Finally, under the Third Circuit's recent decision in *Carrera v. Bayer Corp.*, 727 F.3d 300 (3d Cir. 2013) there cannot be an ascertainable class where, as here, a retailer's own records do not enable the defendant to identify the members of the proposed class and there is no otherwise reliable and administratively feasible method to prove class membership. Therefore, the Court should strike the claim brought on behalf of a putative class of purchasers, pursuant to Rule 23(d)(1), Fed. R. Civ. P.

STATEMENT OF FACTS

A. Plaintiff's Allegations

Bonnie Cooper, the single individual plaintiff, alleges that Wal-Mart has violated the CFA in connection with the marketing and sale of Equate Migraine, which is Wal-Mart's private-brand migraine relief medication. Specifically, plaintiff alleges that Wal-Mart charges more than twice as much for Equate Migraine as it does for Equate Headache (Complaint ("Compl.") ¶ 14), and that Wal-Mart markets Equate Migraine as specifically designed to treat migraines (*Id.*,

¶ 16), despite the fact that Equate Migraine and Equate Headache contain the same ingredients in the same amounts – 250 mg of acetaminophen, 250 mg of aspirin, and 65 mg of caffeine. (*Id.*, ¶14). On that basis, Plaintiff alleges that the two products are "the same medicines." *Id.*, ¶ 14.

Plaintiff further alleges that the website description on walmart.com of the Equate Headache product – the product she did **not** buy – "falsely lists" the active ingredient as only acetaminophen, without listing the other two active ingredients. *Id.*, ¶ 15. As support for that allegation, the Complaint attaches as Exhibit A information from the walmart.com website relating to Equate Headache. In Exhibit A, the same website page that lists only Acetaminophen under "Active Ingredients" in the "Drug Facts" section of the page also shows in larger font the packaging that lists all three active ingredients. Further, the "Item Description" on the same website page, immediately below the "Drug Facts" section, lists all three active ingredients. Compl., Ex. A. The Complaint itself includes pictures of both the products, citing the walmart.com website as the source of those photographs. In both photos, all three of the active ingredients are clearly shown on the products' packaging. *See Id.*, ¶¶ 12-13.

Plaintiff alleges that she was deceived into purchasing Equate Migraine by Wal-Mart's packaging, website and pricing, all of which she claims led her to believe that the product was more effective for migraine than Equate Headache

(*Id.*, ¶¶ 16-18). Specifically, plaintiff alleges that "[s]he purchased the medicine [Equate Migraine] after viewing the packaging, website, and the price charged, which led her to believe that Equate Migraine was a more powerful medicine for migraines than Equate Headache, and was therefore worth paying the extra cost." *Id.* ¶ 5. She claims an ascertainable loss of $5.22 (the difference in price between Equate Headache and Equate Migraine). *Id.* ¶ 32.

The Complaint includes a single count for violation of the New Jersey Consumer Fraud Act, alleging that Wal-Mart's conduct with respect to the marketing of Equate Migraine "constitutes an unconscionable commercial practice, deception, fraud, false pretense, [and] misrepresentation of material facts." Complaint ¶ 30.

B. Class Allegations

Plaintiff purports to represent a putative NJ state-wide class consisting of:

> All citizens of the State of New Jersey who purchased Wal-Mart's Equate Migraine in New Jersey at anytime from September 15, 2007 to the present (the "Class Period").

Complaint at ¶ 19. The Complaint does not explain how Plaintiff alleges the class members could be identified.

C. The FDA Regulatory Process Applicable to Equate Migraine Is Different From The FDA Regulatory Process Applicable to Equate Headache

While Equate Headache and Equate Migraine contain the same active ingredients, since they have different intended uses (*i.e.*, one treats migraines and the other ordinary headaches), under FDA rules, as noted above, they are different products and are subject to substantially different regulatory regimes and requirements.[1]

1. The Application and Approval Process for New Drugs

The labeling of all drugs, including both Equate drugs, is highly regulated by the FDA, and is part and parcel of the way in which a drug enters the market. For

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[1] As discussed below, Equate Headache is a "monograph" drug, whereas Equate Migraine is non-monograph and subject to a different approval regimen. The difference is described on the FDA website as follows:

"OTC drugs can be brought to the market following the [New Drug Application] process as described above or under an OTC monograph. **Each OTC drug monograph is a kind of "recipe book" covering acceptable ingredients, doses, formulations, labeling, and, in some cases, testing parameters**. OTC drug monographs are continually updated to add additional ingredients and labeling as needed. **Products conforming to a monograph may be marketed without FDA pre-approval**. The NDA and monograph processes can be used to introduce new ingredients into the OTC marketplace."

See Certification of David E. Sellinger dated November 7, 2013 ("Sellinger Cert."), Exhibit A (copy of page available at http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/default.htm). OTC drugs for the treatment of migraine are non-monograph drugs, and therefore subject to the New Drug Application Process.

a manufacturer seeking to market a drug, the approval process can be divided into two separate processes which are distinguished by whether or not a manufacturer is required to obtain FDA pre-approval prior to marketing a drug. The process requiring pre-approval is characterized by either a new drug application ("NDA") or an abbreviated new drug application ("ANDA").

a. New Drug Applications

First, a drug can come to market through an approved new drug application ("NDA") under FDCA § 505(b)(1) or (b)(2). To gain approval, a manufacturer must provide the FDA with sufficient animal data and clinical data, in the form of human clinical trials frequently involving hundreds to thousands of human subjects, to assure that the drug is both safe and effective for its intended use.

Drugs are evaluated and approved on the basis of the ailment that they claim to treat. In that regard, a single chemical that is separately marketed in two versions, one to treat one ailment and another to treat a separate ailment, are not "the same drug," as far as FDA is concerned even though they are chemically identical. Two drugs are deemed to be the "same" if and only if they contain the same active ingredient as a previously approved drug and "is intended for the same

use as the previously approved drug." 21 C.F.R. § 316.3(b)(13(i) & (ii) (defining term "same drug" for purposes of the Orphan Drug Act).[2]

b. Abbreviated New Drug Applications

Second, a drug can come to market after FDA approval of an abbreviated new drug application ("ANDA") under FDCA § 505(j). This FDA process had its genesis in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, commonly referred to as "Hatch-Waxman," which established a streamlined procedure for FDA approval of generic drugs. "Under this procedure, the original applicant for FDA approval of a drug, called the 'pioneer' [or brand-name] applicant must still complete a full NDA. However, subsequent applicants who wish to manufacture generic versions of the original have an alternative: they may instead complete an ANDA, which relies on the FDA's previous determination that the drug is safe and effective, and thus avoid submitting new safety and effectiveness studies." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (Fed. Cir. 1998). However, the sponsor of a generic drug must still perform animal studies and undertake the expense of limited clinical trials to demonstrate that its generic drug is bioequivalent to an existing NDA-approved brand-name drug. "A generic drug application must also 'show that the

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2 Thus, by way of example, the drug finasteride is marketed under the name Proscar(r) when labeled to treat an enlarged prostate and under the name Propecia(r) when labeled to treat male pattern baldness. Both are manufactured and distributed by Merck Sharp & Dohme Corp.

[safety and efficacy] labeling proposed ... is the same as the labeling approved for the [brand-name] drug.' § 355(j)(2)(A)(v); *see also* § 355(j)(4)(G); Beers §§ 3.01, 3.03[A]." *PLIVA, Inc. v. Mensing*, ___U.S.___, 131 S.Ct. 2567, 2574 (2011). As such, a generic manufacturer is required by the FDCA and its implementing regulations to use precisely the same labeling, except for the name of the manufacturer, on its generic drug as the brand-name product. *Id.*; FDCA § 505(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

In addition to the bioequivalence and labeling requirements, an ANDA applicant must also make one of four patent-related certifications on the application. Of note, here, is the so-called paragraph (IV) certification, where the applicant certifies "that such patent is invalid or will not be infringed by the … new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon receipt of paragraph (IV) certification, the FDA notifies the manufacturer of the pioneer drug of the pending ANDA and the certification. The pioneer manufacturer then has 45 days to institute a patent infringement suit against the generic applicant. *See* 21 C.F.R. § 314.107(b)(23). Once that suit is filed, the FDA is prohibited from approving the ANDA application for 30 months or until the matter is resolved favorably to the applicant, whichever occurs first. *See id.*

2. Monograph Drugs

In contrast to drugs which may only be marketed through a premarket approval process (*i.e.*, NDA, ANDA) are those over-the-counter drugs which are generally recognized as safe and effective (GRASE) by the FDA and published as such either as a final or as a tentative final monograph; these drugs are referred to as OTC final monograph drugs and appear in 21 C.F.R. pts. 330-369 or in separate uncodified provisions published in the Federal Register. OTC monograph drugs usually do not require upfront FDA approval, and the regulations exist as an approved "recipe." *See* 21 C.F.R. § 330.1 ("General conditions for general recognition as safe, effective and not misbranded"). A manufacturer seeking to sell such a drug is permitted to do so without submitting a new drug application provided the drug is manufactured pursuant to the "recipe" set forth in the FDA monograph. Thus, the manufacturer of a monograph drug can distribute its product without prior approval provided that it is chemically identical to a monograph drug, is labeled for the same intended use as set out in the monograph and carries all of the warnings required for that drug by the monograph.

3. The Regulatory Requirements for Equate Migraine

Equate Migraine, which is labeled to treat migraines, is sold pursuant to an approved ANDA obtained by the manufacturer L. Perrigo Co. on November 26, 2001, after it had completed clinical trials demonstrating bioequivalence (21

C.F.R. § 314.94(a)(7)), demonstrated that its manufacturing facilities were in accord with FDA's "chemistry, manufacturing, and controls" requirements (21 C.F.R. § 314.94(a)(9)), executed a paragraph (iv) certification, and underwritten the expense of the ensuing patent litigation with Bristol-Myers Squibb ("BMS"), the maker of Excedrin Migraine, which ended when Perrigo agreed to license the drug from BMS, the owner of the patent on the pioneer product.[3] According to the FDA letter approving Perrigo's ANDA, "Perrigo entered into a license agreement with the Bristol Myers Squibb Company granting Perrigo certain rights, including the right to market products containing the combination of aspirin, acetaminophen, and caffeine with a label claim for the treatment of migraine."[4] *See* ANDA

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[3] The pioneer product, Excedrin® Migraine, was approved by the FDA pursuant to NDA on January 14, 1998. The original NDA applicant and manufacturer was Bristol-Myers Squibb ("BMS"). In 2005, BMS sold all of its OTC drugs to Novartis which currently manufactures and distributes all Excedrin branded products. *See* BMS 1998 Form 10-K at 26; BMS 2005 Form 10-K, at 2. Relevant portions of the 1998 and 2005 BMS Forms are attached to the Sellinger Cert. as **Exhibit B.**

[4] The Court may properly take judicial notice of information made publicly-available regarding this regulatory scheme, including information relating to the processes and procedures relating to new drug applications and the marketing and labeling of drugs subject to FDA approval published on the FDA's website. *See Desai v. Sorin CRM USA, Inc.*, Civ. No. 12-2995, 2013 WL 163298 *4 (D.N.J. Jan. 15, 2013) (taking judicial notice of FDA website*); In re Wellbutrin SR/Zyban Antitrust Lit.*, 281 F.Supp.2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of report published in FDA website). *See also Anspach v. City of Philadelphia, Dep't of Pub. Health*, 503 F.3d 256, 273 n.11 (3d Cir. 2007) (taking judicial notice of FDA announcement regarding safety and efficacy of oral contraceptives).

Approval Letter (Nov. 26, 2001) a copy of which is attached as **Exhibit C** to the Certification of David E. Sellinger.[5] According to FDA, the pioneer patent does not expire until July 2017. *See* ANDA Approval Letter.

4. The Regulatory Requirements for Equate Headache

Even though Equate Headache and Equate Migraine contain the same active ingredients, they have different intended uses, and are therefore different products under the FDCA and subject to substantially different regulatory requirements.

Equate Headache is labeled to treat headache, muscle ache, toothache, but is not labeled to treat migraines. In contrast to Equate Migraine, Equate Headache is

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The FDA's public website describes the processes and procedures relating to new drug applications and marketing in some detail. *See, e.g.*:

> http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm (describing the means by which OTC drugs can be brought to market) (Sellinger Cert., **Exh. A**);
>
> http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106342.htm (describing the two FDA divisions that regulate all over the counter drug products in the United States, and noting that the Center for Drug Evaluation and Research ("CDER") "oversees OTC drugs to ensure that they are properly labeled") (Sellinger Cert., **Exh. D**).

[5] A copy of the November 26, 2011 ANDA Approval Letter is publicly available on line at the following URL address:

> http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=5&ved=0CEQQFjAE&url=http%3A%2F%2Fwww.accessdata.fda.gov%2Fdrugsatfda_docs%2Fappletter%2F2001%2F75794apdF.pdf&ei=Pot5UsP8HcjyqQGMsYG4AQ&usg=AFQjCNEAbEDTF4eVVltmgRitBAC7Xz4cCw&sig2=2Rv5jd3Dfv7Z3VcsjwJSRQ&bvm=bv.55980276,d.aWM

sold pursuant to an OTC monograph and was never subject to FDA's premarket approval processes--either NDA or ANDA. *See* 21 C.F.R. § 341.40(a) (permitting use of acetaminophen in combination with aspirin) 42 Fed. Reg. 35,346, 35,371 (col. b) (July 8, 1977); 21 C.F.R. § 343.1 ("An over-the-counter analgesic-antipyretic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1 of this chapter."). Equate Headache compares to Excedrin Headache, manufactured by Novartis. Since there is no outstanding patent listed in the FDA's Orange Book for this product, there was no patent litigation and no licensing fees due. Thus, Equate Headache can be distributed without its manufacturer having to file an NDA or ANDA, without having to conduct any costly clinical trials, without having to underwrite any patent litigation and without having to pay any licensing fees. Even though Equate Headache is distributed pursuant to a monograph, the labeling must comply with FDA requirements. *See e.g.*, 21 CFR 330.1(c); 64 Fed. Reg. 13, 254 (March 17, 1999) (delineating rules for labeling OTC products).

ARGUMENT

I. Plaintiff's Consumer Fraud Act Claim Should Be Dismissed As Preempted By Federal Law

A. The Motion To Dismiss Standard

When reviewing a motion to dismiss, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny,* 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In *Bell Atlantic Corporation v. Twombly,* 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. The factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Id.* at 555, 127 S.Ct. 1955. As the Third Circuit has stated, "[t]he Supreme Court's *Twombly* formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips,* 515 F.3d at 234 (quoting *Twombly,* 550 U.S. at 556, 127 S.Ct. 1955).

In affirming that *Twombly* standards apply to all motions to dismiss, the Supreme Court has subsequently explained the following principles. "First, the

tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009); *Fowler v. UPMC Shadyside,* 578 F.3d 203, 210–11 (3d Cir.2009). "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 1950. The plausibility standard requires that "the plaintiff plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and demands "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal,* 129 S.Ct. at 1949 (quoting *Twombly,* 550 U.S. at 556, 127 S.Ct. 1955). Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Fowler,* 578 F.3d at 211.

In evaluating a motion to dismiss, a court may consider the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon these documents. *Pension Benefit Guar. Corp. v. White Consol. Indus.,* 998 F.2d 1192, 1196 (3d Cir. 1993).

Applying these familiar standards, Plaintiff's Complaint must be dismissed for failure to state a claim.

B. Plaintiff's Claim Is Preempted By The FDCA and Applicable Regulations

Plaintiff's claims regarding Equate Migraine are preempted by the requirements of the FDCA, 21 U.S.C. § 301 *et seq*. *See also PLIVA Inc. v. Mensing*, 564 U.S. ___ ,131 S.Ct. 2567 (2011). The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Where state and federal law "directly conflict," state law must give way. *Wyeth v. Levine*, 555 U.S. 555, 583 (2009); *see also Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000) ("[S]tate law is naturally preempted to the extent of any conflict with a federal statute"). The Supreme Court has also held that state and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (internal quotation marks omitted).

Here, the underlying theory of Plaintiff's claim is that Wal-Mart was (1) prohibited under the New Jersey Consumer Fraud Act from selling Equate Migraine with the claim on the label that the product is effective in providing migraine relief, or (2) required to sell Equate Headache with the claim that it was as effective as Equate Migraine in providing migraine relief. The fallacy in the Complaint is that both premises run afoul of the federal regulatory process pursuant to the FDCA. If Wal-Mart had done what Plaintiff claims should have

been done with the labeling on either Equate Migraine or Equate Headache, Wal-Mart would have violated federal law.

Plaintiff's state-law claims in this case seek to impose state law requirements that are both expressly preempted under § 379r of the Food, Drug, and Cosmetic Act ("FDCA") and impliedly preempted by the FDA's labeling requirements. Section 379r(a) provides that states may not establish "any requirement ... (1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]...." 21U.S.C. § 379r(a). Congress has therefore mandated that states may not create requirements different from the FDCA's requirements. *See Crozier v Johnson & Johnson*, 901 F.Supp.2d 494, 503 (D.N.J. 2012). Thus, any attempt to apply New Jersey law to compel a manufacturer to add to its product's label statements not expressly authorized by the approval letter or monograph is pre-empted. Also, any attempt to add "intended uses" to a product (*e.g.*, treats both pain and migraines) or otherwise tamper with the label is also expressly preempted.

The New Jersey law to the extent it is being applied to affect a drug's label is also impliedly preempted under conflict preemption. *See Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984) (where state and federal laws are mutually inconsistent, state law is preempted). As to Equate Migraine, the FDCA expressly prevents a manufacturer of a generic product from adding anything to its label that

is not present on the label of the approved pioneer. *See, e.g.*, 21 CFR § 314.150(b)(10). Therefore, both Perrigo and Walmart are prohibited from altering the label of Equate Migraine. Conversely, New Jersey law may not be used to compel a manufacturer or distributor to modify a monograph label to include claims (*e.g.*, treats migraine) that would require a separate ANDA, as would be the case if the manufacturer added a migraine claim to Equate Headache. Adding unapproved claims to a product's label is prohibited by the FDCA.[6]

In *PLIVA*, the Supreme Court considered claims against a generic drug manufacturer, which alleged that the manufacturer was liable for failing to disclose alleged risks on the product label in violation of the Louisiana Products Liability Act (LPLA) and Minnesota tort law. *Id.* at 2573. The Supreme Court concluded that federal law preempted state laws regarding the duty of a generic drug manufacturer to change a drug's label. *Id.* at 2577-78. In doing so, the Court noted that the FDA interprets its regulations to require that the labels of a brand name drug and its generic copy must always be the same – thus, generic drug manufacturers have an ongoing federal duty of "sameness." *Id.* at 2575. The

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[6] Recently, for example, according to the FDA, Abbott Laboratories agreed "to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the Food and Drug Administration." See Sellinger Cert., **Exh. E** (May 7, 2012 press release, publicly-available at: http://www.fda.gov/ICECI/CriminalInvestigations/ucm303539.htm

Court explained that the manufacturers could not change the labels on their products in response to state law without running afoul of their duty to comply with FDA regulations:

> It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.
>
> If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [Plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. *See, e.g.*, 21 CFR § 314.150(b)(10). Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Id. at 2577-78.

PLIVA is controlling here, and should compel the same result. Plaintiff's claim regarding the use of the term "Migraine" and the migraine relief claim on the product label for Equate Migraine, and the absence of such term and product claim on the product label for Equate Headache, are preempted by Federal law. Indeed, recently, the FDA concluded that a drug manufacturer who labeled its OTC analgesic as relieving pain from both headaches and migraines was misbranded under FDCA § 502(f)(1) because no product providing that combination of relief is

listed in any monograph.[7] Yet, this is precisely what plaintiff believes defendant ought to have done in this case. Thus, it would not be possible for Wal-Mart to obey the FDA's labeling requirements and simultaneously heed plaintiff's interpretation of New Jersey law. Therefore, to the extent that Plaintiff's interpretation of New Jersey law would require labels to be changed, New Jersey law is preempted.

C. The FDA Has Primary Jurisdiction Over Plaintiff's Claims

Plaintiff's claim in this case, which relates to the labeling of an over-the-counter pain reliever, is not only preempted but also runs afoul of the doctrine of primary jurisdiction. *See MCI Telecommunications Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (3d Cir. 1995); *Clark v. Actavis Group*, 567 F. Supp. 2d 711, (D.N.J. 2008) (judicial abstention warranted under doctrine of primary jurisdiction where relief sought by class action involved matters within realm of FDA's authority).

Primary jurisdiction "'applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.' " *Greate Bay Hotel & Casino v. Tose*, 34

[7] *See* Sellinger Cert., **Exhibit F**, FDA warning letter publicly-available at: http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm248256.htm

F.3d 1227, 1230 n.5 (3d Cir. 1994), quoting *Boss v. Rockland Elec. Co.*, 95 N.J. 33, 468 A.2d 1055, 1059 (1983). *See also Clark, supra*, 567 F. Supp. 2d at 714-15; *U.S. v. Omega Inst.*, 11 F. Supp. 2d 555, 560 (D.N.J. 1998) (doctrine applies where a claim "requires the resolution of issues that, under a regulatory scheme, have been placed within the special competence of an administrative body.") (*citing U.S. v. Western Pac. R. Co.*, 352 U.S. 59, 63-64 (1956)).

The primary jurisdiction doctrine "requires [a court] to suspend further judicial proceedings, pending referral of the issues for an administrative ruling." *U.S. v. Omega*, 11 F. Supp. 2d at 560 (*citing Reiter v. Cooper*, 507 U.S. 258, 268 (1993)). The "strong policy reasons" behind the doctrine include the fact that "an administrative agency may be uniquely qualified to resolve certain complexities that are outside the conventional experience of the courts," and "judicial economy will be served where the dispute may be decided within the agency, thus obviating the need for court intervention." *U.S. v. Omega*, supra, 11 F. Supp. 2d at 560.

In this case, Plaintiff's Complaint asserts a claim based on the labeling of the Equate Migraine product (and related contentions regarding the labeling on the Equate Headache product), which (as discussed in Section C of the Statement of Facts, above) is the subject of a detailed and comprehensive regulatory process enforced by the FDA. This court should decline jurisdiction over Plaintiff's claim, and stay further proceedings in this case, pending referral of the issues to the FDA

for an administrative ruling, so as to avoid issuing a ruling that would conflict with applicable FDA regulations. Plaintiff's complaint regarding the labeling of this product could be addressed by way of a Citizen Petition, which may be brought pursuant to 21 C.F.R. § 10.30, to ask the FDA to issue, amend, or revoke a regulation, or to change the labeling of products.

II. Plaintiff's Consumer Fraud Act Claims Should Be Dismissed for Failure to State a Claim Under the Consumer Fraud Act

A. The Requirements of The New Jersey Consumer Fraud Act

To state a prima facie case under the CFA, a plaintiff must demonstrate three elements: (1) unlawful conduct by the defendant; (2) an ascertainable loss by the plaintiff; and (3) a causal connection between the defendant's unlawful conduct and the plaintiff's ascertainable loss. *Bosland v. Warnock Dodge, Inc.*, 197 N.J. 543, 964 A.2d 741, 749 (2009). *See also Payan v. GreenPoint Mortg. Funding, Inc.* 681 F.Supp.2d 564 (D.N.J. 2010).

In order to plead an "unlawful practice," the Plaintiff must show an affirmative act, a knowing omission, or a regulatory violation. *Adamson v. Ortho-McNeil Pharma., Inc.*, 463 F.Supp.2d 496, 501 (D.N.J. 2006), *citing Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 17 (1994). *See also* N.J.S.A. § 56:8-2. *See also Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 703 (D.N.J 2011) (claim of affirmative act of deception or fraud requires plaintiff to show that "defendant's statements on its products are false."). Further, when the alleged misconduct consists of an

omission, the plaintiff must also demonstrate the defendant's intent. *See Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 647 A.2d 454, 462 (1994). In addition, where the plaintiff is asserting that an act or omission constitutes an "unconscionable" commercial practice, the plaintiff must plead that the conduct has a tendency to mislead. *See Kugler v. Romain*, 58 N.J. 522, 544 (1971) ("[I]in consumer goods transactions . . . unconscionability must be equated with the concepts of deception, fraud, false pretense, misrepresentation, concealment and the like, which are stamped unlawful under N.J.S.A. 56:8-2.").

Regarding the second element, ascertainable loss, the plaintiff must show that he or she has "suffer[ed] a definite, certain and measurable loss, rather than one that is merely theoretical." *Cox, supra*, 647 A.2d at 462; *see Weinberg v. Sprint Corp.*, 173 N.J. 233, 237, 801 A.2d 281, 283 (2002) ("[T]o have standing under the [CFA] a private party must plead a claim of ascertainable loss that is capable of surviving a motion for summary judgment."). There is no "ascertainable loss" where a plaintiff receives the product that he or she paid for. *See Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 704 (D.N.J 2011) ("When plaintiffs purchased Diet Coke Plus, they received a beverage that contained the ingredients listed on its label.")

CFA claims "sounding in fraud," such as this one, are also subject to the particularity requirements of Federal Rule of Civil Procedure 9(b). *See Naporano Iron & Metal Co. v. Am. Crane Co.*, 79 F.Supp.2d 494, 510 (D.N.J. 2000).

B. Plaintiff Fails To Allege A Violation Of The CFA

In this case, Plaintiff alleges that Wal-Mart's actions with regard to the marketing of Equate Migraine amount to "fraud" and were deceptive and misleading in creating the impression, which Plaintiff alleges is false, that Equate Migraine is more effective at treating migraines than the Equate Headache product. Complaint ¶¶ 30, 31. Importantly, however, Plaintiff does not allege that Wal-Mart misrepresented the active ingredients of Equate Migraine on its packaging or on the walmart.com website. Instead, Plaintiff relies on (1) the mistaken contention that Equate Migraine and Equate Headache are the "same product" and (2) the price differential between Equate Migraine and Equate Headache as evidence of the alleged "fraud," and alleges that Wal-Mart's website description of a different product, Equate Headache (which she did not purchase), did not list all of the ingredients in that product. Neither of these contentions has any merit.[8]

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[8] While Plaintiff describes her claim with reference to the pricing and packaging of both Equate Migraine and Equate Headache, she only purchased the Equate Migraine product. Therefore, she only has standing to assert a claim relating to Equate Migraine. *See Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275, 281 (D.N.J. 2011) (Plaintiff did not have standing to pursue a claim regarding coffee-brewing products he neither purchased nor used), *citing Lieberson v. Johnson & Johnson*, 865 F.Supp.2d 529, 537 (D.N.J. 2011) (class

1. Plaintiff's Contention that Equate Headache and Equate Migraine are the Same Product is Contrary to Controlling Federal Law.

Plaintiff repeatedly alleges in her Complaint that Equate Migraine and Equate Headache are the same product. *See, e.g.*, Compl. ¶¶ 14, 16 (Equate Migraine and Equate Headache are "the same medicines"; Wal-Mart puts "the same medicine into different color packaging"). However, as noted above, under federal law the two products do not satisfy the definition of "same drug," which requires not only chemical identity, but also that the two have the same intended uses. *See, e.g.,* 21 C.F.R. § 316.3(b)(13(i) & (ii). That Equate Headache and Equate Migraine have the same ingredients does not mean that they are the "same drug" as a matter of controlling federal law and regulations.

2. Plaintiff Has Not Suffered A Loss By Her Purchase Of Equate Migraine.

In this case, the plaintiff paid for Equate Migraine and received Equate Migraine. There is no "ascertainable loss" where a plaintiff receives the product that he or she paid for. *See Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 704 (D.N.J 2011) ("When plaintiffs purchased Diet Coke Plus, they received a beverage that contained the ingredients listed on its label."). *See also Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (3d Cir. 2010) (affirming dismissal

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action plaintiff did not have standing to assert claims regarding bath products she did not purchase).

of CFA claim for failure to demonstrate concrete injury-in-fact where plaintiff failed to allege "that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect"); *Adamson, supra*, 463 F.Supp.2d at 505 (Plaintiff cannot state a claim for unjust enrichment where she chose not to purchase authorized generic version of drug); *Arcand v. Brother Int'l Corp.*, 673 F.Supp.2d 282, 301 (D.N.J. 2009) (dismissing CFA claim based on purchase of printer cartridges that plaintiffs expected to last longer, and noting that "[i]n evaluating whether a plaintiff has suffered an ascertainable loss, the Court need not countenance 'hypothetical or illusory' losses or the wholly subjective expectations of a consumer" regarding a product); *Solo v. Bed Bath & Beyond, Inc.*, No. 06–1908(SRC), 2007 WL 1237825, *3 (D.N.J. Apr. 26, 2007) (dismissing CFA claim based on purchase of sheets where plaintiff failed to "specifically allege that what he did receive[ ] was of lesser value than what was promised, *i.e.*, that the sheets he received were worth an amount of money less than the sheets he was promised, or that he experienced a measurable out-of-pocket loss because of his purchase."); *Franulovic v. Coca–Cola Company*, No. 07–539(RMB), 2007 WL 3166953, *8-9 (D.N.J. Oct. 25, 2007) (dismissing CFA claims where plaintiffs did not allege that they did not "enjoy the advertised benefit" of the beverage they purchased).

There is no claim in this case that Equate Migraine failed to provide plaintiff with headache relief, or otherwise did not convey the benefits advertised. What plaintiff is seeking in this case is a windfall based on the allegation that there is another, less expensive product in the marketplace that she believes she would have found equally satisfactory. *See Arcand, supra,* 673 F.Supp.2d at 302 ("[T]he notion that the [Consumer Fraud] Act provides a windfall to consumers or should be interpreted in such a way as to run afoul of the adage that, a consumer is only entitled to what he pays for, is unsupported by the applicable case law and the corresponding legislative history.").

3. None Of The Statements Regarding The Equate Migraine Product Are Alleged To Be False.

Upon examination, Plaintiff's specific complaints regarding Wal-Mart's marketing of Equate Migraine do not contain any allegation of a false or misleading statement regarding the product itself. Most importantly, the use of the term "Migraine" and the migraine relief claim on the packaging was not misleading, because the product is indicated for treatment of migraine and the manufacturer has used the language required by the FDA in compliance with the relevant FDA regulations. The manufacturer is expressly prohibited from changing any of that language. *See* discussion above at Section I.B. Furthermore, although the Complaint alleges that the use of "bold-type name across the box," and a different color in the packaging of Equate Migraine (*see* Complaint ¶¶ 2, 16)

were somehow misleading, these do not amount to false statements or omissions. In any event, Wal-Mart has "no duty to advertise in a particular manner," so long as its advertisements were not misleading, and there is no allegation that any of the statements made about Equate Migraine, including its list of ingredients, were incorrect. *Adamson*, 463 F.Supp.2d at 505.

Plaintiff's only allegation regarding an alleged incorrect statement about any product relates to Equate Headache, a product plaintiff did not even purchase, which plaintiff claims is advertised on Wal-Mart's website without a complete list of active ingredients. *See* Complaint ¶ 15. Specifically, Plaintiff alleges that class members are led to believe by one specific portion of the page describing Equate Headache (the "Drug Facts" box) that Equate Headache contained only one ingredient (acetaminophen) rather than three (acetaminophen, aspirin and caffeine.) *Id.*[9] Belying that allegation, the same web page that Plaintiff attaches to her Complaint describes the product as "Equate Extra-Strength Headache Relief Tablets, **Acetaminophen, Aspirin, Caffeine**," (emphasis added); contains a photo of the packaging expressly listing all three ingredients; and also lists all three

[9] Curiously, however, while Plaintiff alleges that she read the "website" which was one of the sources for her alleged belief that Equate Migraine was a more powerful medicine for migraines than Equate Headache", Compl. ¶ 5, she does not specifically allege that she ever read that portion of the website page.

ingredients under the "Item Description" and again in the bullet-point list of product characteristics. Complaint, Exhibit A.

Furthermore, there is no claim that the box and label of Equate Headache did not list all three ingredients in their respective amounts. Given the number of times all three ingredients were disclosed, in multiple locations, on the web page, there can be no plausible allegation of any intent to mislead. Therefore, because the facts alleged in the Complaint are insufficient to demonstrate that Wal-Mart intended to mislead Plaintiff (or any other purchaser of Equate Headache or Equate Migraine), she cannot maintain a CFA claim based on an omission, and her claim must be dismissed. *See Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 647 A.2d 454, 462 (1994). Nor is it even plausible under the *Twombly / Iqbal* standard that any purchaser would be misled by the website description.

4. Price Differential Alone Is Insufficient To State A Claim.

There is no basis to claim that a price differential between two different products can support a claim for misleading marketing, much less "fraud." In fact, this Court has recognized that such allegations are insufficient to state a claim where, as here, there are other explanations for the price differential. *See Crozier v Johnson & Johnson*, 901 F.Supp.2d 494 (D.N.J. 2012) (dismissing CFA claims regarding marketing and sale of antiseptic nasal spray).

In *Crozier*, the plaintiffs alleged a violation of the CFA based on the advertisement and marketing of Neosporin "NEO TO GO!" first aid antiseptic spray, which was sold at a higher price than other, similar antiseptic sprays. *Id.* at 496-97. Much like the "price differential" claim plaintiff attempts to assert in this case, the plaintiffs in *Crozier* alleged that "[t]he extraordinary and unreasonable price differential between the subject spray and common antiseptic products can only be explained by the fact that Johnson & Johnson has intentionally, recklessly, and/or negligently misled consumers into believing that the subject spray contains antibiotic ingredients," and that consumers believed that "they are paying a higher price for the extra infection prevention that is provided by an antibiotic, when in fact the spray contains no antibiotics whatsoever." *Id.* at 497.

The Court in *Crozier* first concluded that plaintiffs' claims regarding the contents of the product label were preempted by Federal law (as they are in this case, as discussed more fully in Section I, above). *Crozier*, 901 F.Supp.2d at 504. With regard to the "price differential" claim, the court also found that the price differential could be explained by factors other than an attempt to mislead, and therefore did not support plaintiffs' allegations:

> [T]he Complaints also acknowledge that the spray is sold in spray bottles and "is specifically designed to fit anywhere to give you infection protection anytime, anywhere." (Id. ¶ 35.) Plaintiffs' own statements discount their assertion that the price differential can "only" be explained by misleading advertising that implied that the spray contained antibiotics.

> The spray's convenience and portability can also explain the price differential.

Id. at 506-7 (emphasis added).

In this case, the price differential between Equate Migraine and Equate Headache is not based on convenience or portability, but the same underlying principle applies. The price differential in this case reflects the fact that the two products are subject to different regulatory requirements, and the fact that Wal-Mart had to obtain Equate Migraine from a supplier that had gone through the ANDA approval process, whereas there is no such requirement for Equate Headache, which is a monograph drug. More specifically, as noted above, in order to obtain approval of its ANDA, Perrigo had to complete clinical trials demonstrating bioequivalence; demonstrate that its manufacturing facilities were in accord with FDA requirements; underwrite the expense of the ensuing patent litigation with BMS; and agree to pay licensing royalties for the drug from BMS. *See* Section C(1)(b) of Statement of Facts, *supra*. Those costs associated with being subject to the regulatory process are set forth in the ANDA Approval Letter. (*See* Sellinger Cert., Ex. C). In contrast, the manufacturer of Equate Headache did not have to file an ANDA; did not have to conduct any costly clinical trials; did not have to underwrite any patent litigation; and did not have to pay any licensing fees. Therefore, the price differential in this case, like the price differential in *Crozier*, has a legitimate explanation that does not support any allegation of fraud.

Adamson v. Ortho-McNeil Pharma., Inc., 463 F.Supp.2d 496 (D.N.J. 2006), is also instructive on the issue of "price differential" claims. The plaintiff in that case alleged a violation of the CFA and a claim for unjust enrichment based on her claim that she was misled into purchasing Ortho Tri-Cyclen, rather than a cheaper generic version of the drug, TriNessa, with identical ingredients. *Id.* at 498. Specifically, the plaintiff claimed that the defendant failed to disclose to the public that its authorized generic, TriNessa, was in fact the same drug, with the same active ingredients, as Ortho Tri-Cyclen, and that she suffered a financial loss by purchasing Ortho Tri-Cyclen, rather than TriNessa, at a lower price. *Id.* at 499.

The Court in *Adamson* found that the plaintiff could not sustain a claim under the CFA because none of the statements made about TriNessa were misleading, *i.e.*, they accurately described the product, or were mere puffery. *Id.* at 503. The same reasoning applies in this case, where plaintiff has not alleged that any of the statements made about Equate Migraine are incorrect as to the active ingredients, indications, or any other aspect of the product.

III. Plaintiff's Class Claims Must Be Stricken Because The Proposed Class Is Not Ascertainable

Plaintiff's Complaint describes the proposed class as:

> All citizens of the State of New Jersey who purchased Wal-Mart's Equate Migraine in New Jersey at anytime from September 15, 2007 to the present (the "Class Period").

Complaint at ¶ 19. This class definition is fatally flawed, however. Where, as here, based on the allegations of the complaint, the complaint on its face demonstrates that a class cannot be certified under the controlling law in this Circuit, a motion will lie, even at the pleadings stage, to strike the class claim pursuant to Rule 23(d)(1)(D), Fed. R. Civ. P.

Rule 23(d)(1)(D) "expressly authorizes a motion to strike class allegations by authorizing the court to issue an order 'requiring that the pleadings be amended to eliminate allegations about representation of absent persons.'" 1 McLaughlin on Class Action § 3:4 (6th ed. 2010) (quoting Fed. R. Civ. P. 23(d)(1)(D)). Such a motion "ordinarily is made solely on the basis of the complaint." *Id.; see also Clark v. McDonald's Corp.*, 213 F.R.D. 198, 205 n.3 (D.N.J. 2003) ("A defendant may move to strike class action allegations prior to discovery in those rare cases where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met."). In this case, Plaintiff's proposed class ("All citizens of the State of New Jersey who purchased Wal-Mart's Equate Migraine in New Jersey at anytime from September 15, 2007 to the present") is not ascertainable. *See Carrera v. Bayer Corp.*, *supra*, 727 F.3d at 306 ("Class ascertainability is 'an essential prerequisite of a class action, at least with respect to actions under Rule 23(b)(3).'"), *quoting Marcus v. BMW*, 687 F.3d 583, 592-93 (3d Cir. 2012).

In *Carrera*, a purposed class action on behalf of purchasers of a diet supplement, the Third Circuit recently held that, in order to meet the ascertainability requirement, a putative class must be administratively feasible, meaning that "identifying class members is a manageable process that does not require much, if any, individual factual inquiry." *Id.* at 307-8, quoting William B. Rubenstein & Alba Conte, *Newberg on Class Actions* § 3:3 (5th ed.2011). "Ascertainability provides due process by requiring that a defendant be able to test the reliability of the evidence submitted to prove class membership," *id.* at 307, and in order to satisfy the ascertainability requirement, a plaintiff "must demonstrate his purported method for ascertaining class members is reliable and administratively feasible, and permits a defendant to challenge the evidence used to prove class membership." *Id.* at 308.

In *Carrera*, the plaintiff proposed to establish class membership using retailer records of sales made with loyalty cards and records of online sales, or by affidavits of class members. *Id.* at 308-09. The Third Circuit rejected both proposed approaches, however, because "[t]here is no evidence that a single purchaser … could be identified using records of customer membership cards or records of online sales," and the argument that the class could be proven by affidavit "fails because it does not address a core concern of ascertainability: that a defendant must be able to challenge class membership." *Id. See also Marcus*, 687

F.3d at 594 (Class members cannot be ascertained just on their "say so."). Similarly, if a class definition "includes a requirement that cannot be proven directly, and that depends instead upon each putative class member's feelings and beliefs, then there is no reliable way to ascertain class membership." *Xavier v. Philip Morris USA, Inc.*, 787 F. Supp. 2d 1075, 1089 (N.D. Cal. 2011).

In this case, Plaintiff cannot meet the ascertainability requirement because there is no feasible method to identify all the individual purchasers of Equate Migraine from Wal-Mart's records, nor is there any other reliable, administratively feasible method that Wal-Mart would be able to test to identify all such purchasers. For example, with respect to customers who purchased the Equate Migraine product at a Wal-Mart store with cash, Wal-Mart would have no way of identifying that purchaser based on Wal-Mart's own records. *See Carrera*, 727 F.3d at 309.

In addition, plaintiff's proposed class, by definition, includes purchasers who were aware that Equate Migraine contained the same ingredients as Equate Headache and were not "misled" by the price differential. *See Oshana v. Coca-Cola Co.*, 472 F.3d 506, 514 (7th Cir. 2006) (class not ascertainable where it "could include millions who were not deceived" by alleged misleading statements, "and thus have no grievance under the [Illinois Consumer Fraud Act]"). These consumers would include those who compared the product packages on the shelf at

the Wal-Mart store, and/or did not rely on the website description for Equate Headache that plaintiff alleges was misleading.

Therefore, determination of the members of a class of purchasers who might have a claim of being misled would require individualized inquiry into the knowledge of each purchaser, and the class therefore is not readily ascertainable based on objective criteria. *See Marcus*, 687 F.3d at 592-93 (Class must be "readily ascertainable based on objective criteria."). Where class members cannot be identified without consideration of individualized issues, the class is impossible to define. *Id. See also Bright v. Asset Acceptance,* 2013 US Dist. LEXIS 108432 *20 (D.N.J. Aug. 1, 2013) (class of consumers called by service not ascertainable).

Moreover, as there is no allegation that the advertisements or packaging of Equate Migraine contained any inaccurate statements, membership in the class would depend to some extent on individual feelings and beliefs, and each individual class member's subjective reaction to the design features of the packaging. Accordingly, because Plaintiff's proposed class is not ascertainable under controlling standards in this Circuit, the class claim should be stricken pursuant to Rule 23(d)(1)(D).

CONCLUSION

For all of the foregoing reasons, Wal-Mart respectfully requests that Plaintiff's Complaint be dismissed in its entirety, with prejudice, for failure to state a claim. In the alternative, Wal-Mart respectfully requests that the class claims be stricken on the ground that the proposed class is neither ascertainable nor administratively feasible.

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